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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Amr Salahieh

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04/17/2008

CROMPTON, SEAGER & TUFTE, LLC

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SUITE 800

MINNEAPOLIS, MN 55403-2420

EXAMINER

EREZO, DARWIN P

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/734,849	<b>Applicant(s)</b> SALAHIEH ET AL.	
	<b>Examiner</b> Darwin P. Erez	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 17-21 and 38-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16, 22-31, 33-37 and 44-46 is/are rejected.
- 7) ☒ Claim(s) 32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. The applicant's amendment filed on 1/21/08 has been entered into the application.

#### ***Claim Objections***

2. Claim 46 is objected to because it depends on itself. On treating the claim on the merit, the claim will be viewed as being dependent upon claim 45.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-3, 5-15 and 22-31, 33 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,203,561 to Ramee et al. in view of US 6,290,710 to Cryer et al. and in further view of US 6,537,294 to Boyle et al.

(claim 1) As shown in Fig. 5A-5B, Ramee discloses a filter system comprising a guide tip **62**; an elongated wire **51** having a distal end attached to the guide tip; an

embolic protection filter **57** disposed along the elongated wire; and an elongated tubular member **61** extending distally to a distal end defining a distal sheath and having a lumen for receiving the elongated wire, wherein the filter is collapsible within the distal sheath (see Fig. 5A).

Ramee is silent with regards to the guide tip having a lumen for receiving a guidewire and the elongated tubular member having another lumen for also receiving a guidewire.

However, the use of a guidewire that is separate from the structure holding the filter is well known in the art. In Fig. 6, Cryer discloses a guide tip **48** having a lumen for receiving a guidewire **38**. Also, Boyle discloses a delivery sheath (an elongated tubular member) defining two lumens, wherein one lumen receives a guidewire and the other lumen receives an elongated wire with a filter (Fig. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Ramee to have the guide tip define a lumen and the elongated tubular member define an additional lumen for receiving a guidewire because the use of a separate guidewire in a filter system is well known in the art, as shown above. Furthermore, it has been held that combining prior art elements according to known methods to yield predictable results would be obvious to one of ordinary skill in the art. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

(claims 2-3 and 5-7) Ramee discloses an atraumatic, tapered guide tip, with the proximal end having a larger profile than the distal portion; wherein the guide tip has a

spring coil (Fig. 5B). It would also be obvious for the spring coil to be radiopaque since it is well known in the art for spring coils to be made of metal.

(claims 8-10 and 44-46) The modified guide tip of Ramee will have a straight lumen similar to that of Cryer. With regards to the guide tip having a curved lumen (parallel proximal portion elongated axis and distal portion elongate axis), a tapered lumen, or a guide tip lumen be proximal to the distal end of the elongated wire, it would be obvious to one of ordinary skill in the art to modify a straight lumen to a curved lumen or a tapered lumen, or have the guide tip lumen be proximal to the distal end of the elongated wire since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

(claims 11-13) The guide tip is connected to the elongated wire at a "joint"; wherein the elongated wire is fitted into the guide tip; and wherein the elongated wire has a spring coil (Fig. 5B).

(claims 14-15) The filter is capable of self-deploying once removed from the distal sheath; wherein the filter has a membrane, a support hoop and an arm.

(claim 22) The modified guide tip of Ramee in view of Cryer is silent with regards to the proximal portion of the guide tip being configured to slide in part within the distal sheath. However, Boyle discloses a filter system wherein the guide tip for the filter is slidable within the distal sheath (Fig . 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Ramee to have the guide tip fit into the distal sheath, as taught by Boyle, because it would allow the guide tip to be deployed together with the distal sheath.

(claims 23-24) Ramee is silent with regards to the distal sheath having skived regions. However, both Cryer and Boyle discloses that distal sheath that have skived regions. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Ramee to have skived regions because it is well known in the art, as disclosed by Cryer and Boyle, and that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

(claim 25) It would be obvious for the device of either Ramee, Cryer or Boyle to have a loading tool for loading the filter into the distal sheath. Furthermore, the applicant does not specify what the loading tool is for. The deployment catheter could be viewed as the loading tool.

(claims 26-30) The modified elongated tubular member of Ramee will have two ports terminating at the distal end. With regards to the second port being located proximally to the first port. it would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to have the second port be located proximally of the first port since the recited limitation does not provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the first and second port being located at the same distance or the claimed limitation because both arrangement will perform the same function of holding the guidewire and the elongated wire.

The applicant's statement in the Remarks filed on 1/21/08 regarding the purpose of the second port being located proximally to the first port does not have support in the originally filed written disclosure.

(claim 31) The guidewire will align the lumen of the guide tip with the lumen of the elongated tubular member.

(claim 33) The modified multilumen deployment sheath (the elongated tubular member) of Ramee can be used as a retrieval sheath once the filter is deployed.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramee et al. in view of Cryer et al. and Boyle et al., as applied to claim 1, and in further view of US 6,371,970 to Khosvari et al.

The modified device of Cryer discloses all the limitations of the claims except for the guide tip having a radiopaque marker band. However, Khosvari discloses a similar invention, wherein a marker band is provided at a guidetip of the device (col. 6, lines 39-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Cryer to include a marker band because it would allow the practitioner to monitor the position of the filter system when deployed within the vascular system.

7. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramee et al. in view of Cryer et al. and Boyle et al., as applied to claim 1, and in further view of US 6,179,861 to Khosvari et al.

The modified device of Cryer discloses all the limitations of the claims except for the support hoop having a radiopaque coil. However, Khosvari discloses a similar

invention, wherein a support hoop is provided with a radiopaque coil (Fig. 10).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the support hoop of Cryer to include a radiopaque coil because it would allow the practitioner to monitor the position of the filter system when deployed within the vascular system.

8. Claims 34-37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramee et al. in view of Cryer et al. and Boyle et al., as applied to claim 1, and in further view of US 2003/0023263 to Krolik et al.

The modified device of Cryer discloses all the limitations of the claims, as seen in the rejection to claim 1, but is silent with regards to a multilumen retrieval sheath having a slit. However, Krolik discloses a multilumen lumen retrieval sheath **146** having a slit **144** for retrieving a filter (the distal end of **145** has multiple lumens). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Cryer to use a retrieval sheath because it would allow the filter to be removed from the vascular system along with any trapped emboli.

***Allowable Subject Matter***

9. Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record fails to teach or render obvious an alignment means



comprising a key disposed on the distal sheath that is adapted to slide within a corresponding groove on the proximal portion of the guide tip.

### ***Response to Arguments***

11. Applicant's arguments with respect to claims 1-16 and 22-31, 33-37 and 44-46 have been considered but are moot in view of the new ground(s) of rejection. The applicant's amendment to further clarify the elongated tubular member extending distally to a distal end defining a distal sheath necessitated the new grounds of rejection.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezzo/  
Primary Examiner, Art Unit 3773